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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/589,229	11/09/2006	Alison Murdoch	36290-0429-00-US (230189)	6660
23973 7590 08/26/2009 DRINKER BIDDLE & REATH ATTN: INTELLECTUAL PROPERTY GROUP ONE LOGAN SQUARE 18TH AND CHERRY STREETS PHILADELPHIA, PA 19103-6996			EXAMINER BARNHART, LORA ELIZABETH	
			ART UNIT 1651	PAPER NUMBER
			MAIL DATE 08/26/2009	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/589,229	Applicant(s) MURDOCH ET AL.	
	Examiner Lora E. Barnhart	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 June 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 47-62 is/are pending in the application.
- 4a) Of the above claim(s) 51-58 and 60-62 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 47-50 and 59 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11/9/06, 11/22/06, 1/22/08</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 47-62 as recited in the preliminary amendment filed 8/11/06 with the application are currently pending.

Election/Restrictions

Applicant's election without traverse of Group I, claims 47-50 and 59, in the reply filed on 6/5/09 is acknowledged. Claims 51-58 and 60-62 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 6/5/09. Examination on the merits will commence at this time on claims 47-50 and 59 ONLY.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 47-50 and 52 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The invention appears to employ novel biological materials, specifically the stem cell line hES-NCL1. Since the biological materials are essential to the claimed invention, they must be obtainable by a repeatable method set forth in the specification or otherwise readily available to the public. If the biological materials are not so

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obtainable or available, the requirements of 35 U.S.C. § 112 may be satisfied by a deposit of the biological materials.

The specification does not disclose a repeatable process to obtain the biological materials, and it is not apparent if the biological materials are readily available to the public. The examiner notes that Applicant has deposited the biological materials (page 4, line 26, et seq.), but **there is no indication in the specification as to public availability**. If the deposit is made under the Budapest Treaty, then an affidavit or declaration by Applicant, or a statement by an attorney of record over his or her signature and registration number, stating that the specific biological materials have been deposited under the Budapest Treaty and that the biological materials will be irrevocably and without restriction or condition released to the public upon the issuance of a patent, would fully satisfy the deposit requirement.

Claim Rejections - 35 USC §§ 102 and 103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 47-50 and 59 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Carpenter et al. (2003, *Cloning and Stem Cells* 5: 79-88; reference U).

Carpenter teaches numerous human embryonic stem cell lines (hES), which are identified by the ES cell markers GCTM-2, TRA-1-60, SSEA-4, OCT-4, hTERT, and TG343 (see Table 1 at page 81 as well as page 82, column 1; and page 84). Carpenter teaches that hES lines generally retain a full complement of chromosomes, including sex chromosomes (page 84, column 1). Carpenter teaches that hES cells have the capacity to form derivatives of all three germ layers both *in vitro* and *in vivo* (page 84, column 2). Carpenter teaches that the laboratory of James Thomson possesses numerous hES cell lines, which are genetically distinct (page 84, column 2); Thomson's laboratory therefore comprises an embryonic stem cell bank. Carpenter teaches contacting hES cells with various agents (e.g., RA and NGF) and monitoring an

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alteration in the cells' metabolism (e.g., differentiation to neurons), thereby concluding the effects of those agents on hES cells (Table 2 at page 85; see also pages 85-86).

The Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether or not applicants' hES line differs, and if so to what extent, from the hES lines discussed in Carpenter. Like the lines of Carpenter, applicants' line expresses GTCM2, TRA-1-60, SSEA-4, OCT-4, hTERT, and TG343 (specification, page 36, lines 17-27). Like the lines of Carpenter, applicants' line is pluripotent *in vivo* (page 36, line 30, through page 37, line 1). Like the lines of Carpenter, applicants' line retains a full complement of chromosomes (page 35, lines 21-24). It is noted that applicants' disclosure characterizes the markers at page 36 as being specific for hES cells (page 13). Furthermore, Stojkovic et al. (2004, *Stem Cells* 22: 790-797; 11/9/06 IDS reference AE) teaches the same cells described herein and indicates that they show "typical expression of ES cell and surface markers" (page 794, last sentence et seq.). The cited art taken as a whole demonstrates a reasonable probability that the hES cell lines of the prior art are either identical or sufficiently similar to the claimed hES cell line that whatever differences exist are not patentably significant. Therefore, the burden of establishing novelty or unobviousness by objective evidence is shifted to applicants.

Merely because a characteristic of a known hES cell line (e.g., differentiation into fibroblasts without formation of embryoid bodies; ability to support growth of undifferentiated cells of the same line) is not disclosed in a reference does not make that cell patentable. The hES cell lines of Carpenter possess inherent characteristics which might not be displayed in the tests used in Carpenter. Clear evidence that the

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hES cell lines of the cited prior art does not possess a critical characteristic that is possessed by the claimed line would advance prosecution and might permit allowance of claims to applicants' line.

No claims are allowed. No claims are free of the art.

Applicant is requested to specifically point out the support for any amendments made to the disclosure in response to this Office action, including the claims (MPEP 714.02 and 2163.06). In doing so, applicant is requested to refer to pages and line numbers in the as-filed specification, **not** the published application. Due to the procedure outlined in MPEP § 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 U.S.C. § 102 or 35 U.S.C. § 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is requested to provide a list of all copending U.S. applications that set forth similar subject matter to the present claims and share an inventor or assignee with the instant application. A copy of such copending claims is requested in response to this Office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lora E. Barnhart whose telephone number is 571-272-1928. The examiner can normally be reached on Monday-Thursday, 9:00am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lora E Barnhart/
Primary Examiner, Art Unit 1651